

ENZYMATIC THERADY 1 んじつ ワトロ おんてたし

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INTEGRATIVE THERAPEUTICS INC.

NF Formulas - PhytoPharmica Tyler Encapsulations - Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 . F: 503.582.0467

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

ZUE.

January 17, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise -	The ingredients in Earth's Promise	Vitamin A (as beta carotene), Vitamin C (from orange fruit
The Goodness of	Orange contain vitamins, minerals,	and sodium ascorbate), Sodium, Potassium (from potassium
Orange	and key compounds that have been	citrate and Fruit and Vegetable Blend), Fruit and Vegetable
-	shown in scientific research to	Blend: orange fruit, whole apple, carrot root juice, carrot root,
	support major body systems.*	banana fruit, apricot fruit, orange fruit juice, sweet potato root,
		mango fruit, tomato fruit, pumpkin fruit extract, butternut
		squash fruit, papaya fruit, cantaloupe fruit, mangosteen fruit,
		Fiber Blend, Inulin from chicory root, Guar Gum Seed Extract,
		Grape (Vitis vinifera) Seed Extract, Stevia Leaf Extract,
		Mixed Bioflavonoids (from citrus fruits), Lycopene, Lutein

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-11-06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Michael P. Devereux Chief Operations Officer

975 0162 LET 17227



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Orange	The ingredients in Earth's Promise Orange are also high in antioxidant activity to help reduce the effects of oxidative stress.*	Vitamin A (as beta carotene), Vitamin C (from orange fruit and sodium ascorbate), Sodium, Potassium (from potassium citrate and Fruit and Vegetable Blend), Fruit and Vegetable Blend: orange fruit, whole apple, carrot root juice, carrot root, banana fruit, apricot fruit, orange fruit juice, sweet potato root, mango fruit, tomato fruit, pumpkin fruit extract, butternut squash fruit, papaya fruit, cantaloupe fruit, mangosteen fruit, Fiber Blend, Inulin from chicory root, Guar Gum Seed Extract, Grape (Vitis vinifera) Seed Extract, Stevia Leaf Extract, Mixed Bioflavonoids (from citrus fruits), Lycopene, Lutein

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Robert Doster

Title: Senior Vice President of Scientific Affairs

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Earth's Promise – The Goodness of Orange	Carotenoids, including beta-carotene and lycopene, a featured nutrient in Earth's promise Orange, are thought to regulate the immune response. In fact, beta-carotene has been studied for its ability to enhance natural killer cell activity.* In another scientific study, beta-carotene from carrots significantly increased antioxidant levels.*	Vitamin A (as beta carotene), Vitamin C (from orange fruit and sodium ascorbate), Sodium, Potassium (from potassium citrate and Fruit and Vegetable Blend), Fruit and Vegetable Blend: orange fruit, whole apple, carrot root juice, carrot root, banana fruit, apricot fruit, orange fruit juice, sweet potato root, mango fruit, tomato fruit, pumpkin fruit extract, butternut squash fruit, papaya fruit, cantaloupe fruit, mangosteen fruit, Fiber Blend, Inulin from chicory root, Guar Gum Seed Extract, Grape (Vitis vinifera) Seed Extract, Stevia Leaf Extract, Mixed Bioflavonoids (from citrus fruits), Lycopene, Lutein

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Michael P. Devereux Chief Operations Officer

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Orange	Vitamin C is one of the best-known vitamins, especially for its support of immune health.*	Vitamin C (from orange fruit and sodium ascorbate),

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Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-11-06

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Orange	Less well-known is the role that vitamin C has in supporting healthy joint and connective tissue.*	Vitamin C (from orange fruit and sodium ascorbate),

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By:

Robert Doster

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Date: 1-11-06

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Orange	Clinical studies have found that high intakes of potassium support normal blood pressure already within the normal limits, and support healthy bone density.*	Potassium (from potassium citrate and Fruit and Vegetable Blend)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-17-06

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Sincerely,



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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Orange	Lutein is deposited in high concentrations in the macular region of the retina. It is believed that this antioxidant plays an important supportive role in eye health by supporting macular pigment development.* Macular pigment absorbs ultraviolet radiation from the sun, among other functions.*	Lutein

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By: KILLULT

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-18-06

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Earth's Promise – The Goodness of Orange	In scientific studies, lutein also supported arterial health.*	Lutein

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By: Kull l'Ilit

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-18-06

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Orange	Lycopene is a potent antioxidant, providing well established support for cardiovascular, prostate, immune and eye health.*	Lycopene

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By: Kuld'l'

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Date: 1-18-06

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Orange	Inulin fiber acts as a prebiotic in the digestive tract, promoting bile excretion and helping foster a healthy climate for probiotic beneficial bacteria. It also aids in the absorption of minerals such as calcium, magnesium and zinc.*	Inulin from chicory root

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By: RICUL

Title: Senior Vice President of Scientific Affairs

Date: 1-18-06

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Earth's Promise – The Goodness of Orange	Soluble and insoluble fiber from inulin also supports healthy digestion and colon function, by safely absorbing and eliminating toxins.*	Inulin from chicory root

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Bv:

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Date:

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Earth's Promise – The Goodness of Orange	Fiber has been demonstrated in numerous clinical studies to provide support of gastrointestinal, cardiovascular, immune, and endocrine function health.*	Vitamin A (as beta carotene), Vitamin C (from orange fruit and sodium ascorbate), Sodium, Potassium (from potassium citrate and Fruit and Vegetable Blend), Fruit and Vegetable Blend: orange fruit, whole apple, carrot root juice, carrot root, banana fruit, apricot fruit, orange fruit juice, sweet potato root, mango fruit, tomato fruit, pumpkin fruit extract, butternut squash fruit, papaya fruit, cantaloupe fruit, mangosteen fruit, Fiber Blend, Inulin from chicory root, Guar Gum Seed Extract, Grape (Vitis vinifera) Seed Extract, Stevia Leaf Extract, Mixed Bioflavonoids (from citrus fruits), Lycopene, Lutein

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Earth's Promise – The Goodness of Orange	In addition to its ability to support the retention of healthy cholesterol levels already within normal limits, guar gum also plays a part in regulating blood glucose levels already within the normal limits.* In a clinical trial, guar gum significantly supported blood glucose levels compared with controls.*	Guar Gum Seed Extract

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Ву:	KLICHŁ			
Robert Doster				

Title: Senior Vice President of Scientific Affairs

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RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH
NAME Earth's Promise —	The inulin and fructooligosaccarides in Earth's	THE CLAIM REFERS Inulin from chicory root
The Goodness of Orange	Promise Orange also support calcium absorption, a crucial factor in maintaining healthy bone density.*	
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I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KLICKLE

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-18-06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.